

Application No. 10/706,128

Reply to Office Action

*REMARKS**Discussion of Claim Amendments*

Claims have been amended to expedite the prosecution of the application. In claim 1, the feature that the composition is "essentially anhydrous" is derived from original claim 19. That the composition is to be administered "without liquid and without chewing" is supported by page 7, lines 26-32 and page 9, lines 31-32, and that the administration is "direct" is supported by page 9, lines 15-21. The amended features concerning the effective amount of the salivation-promoting agent and concerning the replacement of "mass" by "particle paste" are supported by the specification, e.g., page 9, lines 7-14 and original claim 1. Claim 1 has also been amended to the effect that "coated particles" (in the plural) are present, for consistency with the said particle paste which must contain a plurality of such particles. Claims 8-9 and 11-12 have been amended to further sharpen the claim language. Claim 23 has been amended to the effect that the composition is taken without liquid and without chewing. New claim 25 has been added and specifically names types of salivation-promoting agents; here also the term "mass" has been replaced by "particle paste". No new matter has been added by way of these amendments.

Restriction Requirement

Applicant affirms the election with traverse of claims 1-20 and 22-23 for further prosecution. Process claims 21 and 24 remain withdrawn. Applicant respectfully requests rejoinder of the process claims with allowable product claims. New claim 25 belongs in the elected group of invention.

Discussion of Rejections

1. Claims 1, 3, 6-9, 16-20, and 22-23 are rejected under 35 USC 103(a), as allegedly unpatentable over Ventouras (USP 4,882, 169) in view of Schultz (USP 5,167,965). The Office contends that it would have been obvious to one of ordinary skill in the art to provide the sweeteners and/or citric acid of Schultz in the swellable outer layer of Ventouras. The Office also contends that ~~it would have been obvious~~ to one of ordinary skill in the art to vary and/or optimize the amount of the sweetener and/or citric acid according to the guidance provided by Ventouras and Schultz to provide a composition having the desired properties such as taste and/or sweetness. The Office contends that, where the general conditions are

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disclosed in the prior art, it is not inventive to discover the optimum workable ranges by routine experimentation, citing *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Applicant has amended claim 1 to expedite the prosecution, and respectfully submits that the present claims are non-obvious over the cited references. The cited references fail to suggest to those of ordinary skill in the art to arrive at an "amount which is effective, upon said oral administration of the composition, in promoting a flow of saliva which is sufficient to form said coherent, mouldable viscous particle paste within less than 20 seconds", as recited in present claim 1. Ventouras' composition is to be taken orally by first dispersing the composition in water, where each of the particles would gel by absorbing water. Ventouras' composition does not become a mouldable viscous particle paste, rather the particles remain dispersed in water (see col. 2, lines 10-14: "It is therefore the aim of the present invention to provide pellets, which can be manufactured solely from conventional materials known in the art, e.g., from particles of up to e.g. 3.0 mm diameter, which form a perfectly homogeneous dispersion when put into water...").

Further, concerning sucrose, fructose or citric acid, their "amount which is effective, upon said oral administration of the composition, in promoting a flow of saliva which is sufficient to form said coherent, mouldable, viscous particle paste within less than 20 seconds" (instant claim 1) is appreciably higher than what those of skill in the art would consider an optimal amount which is effective for sweetening (sucrose or fructose) or for flavoring (citric acid). For example, see Example 3 of the present application, where the amount of monosodium citrate (acidic salivation-promoting agent) used corresponds to a full 18% by weight of all solids present in the outermost coating (total 550 g coating solids including the 0.5% weight gain by the 6% strength hydroxypropylmethylcellulose, page 38). See also instant Example 8, where the amount of citric acid (acidic salivation-promoting agent) used corresponds to a full 58% by weight of all non-volatiles present in the outermost coating (total 1405 g non-volatiles in the coating, page 41).

Furthermore, amended claim 1 requires that the composition is "essentially anhydrous". The compositions of the instant invention are nevertheless suited for oral administration "without liquid" because of the presence of the salivation-promoting agent

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which generates the required amount of moisture directly via salivation. In contrast thereto, Ventouras teaches that his preparations be put in water first, in order to be suited for oral administration, because otherwise an "unpleasant hoarse feeling" would be perceived (column 4, lines 3-7). Ventouras thus teaches away from "essentially anhydrous pharmaceutical compositions for oral administration without liquid" (instant claim 1). Since Schulz also invariably adds his compositions to an "aqueous carrier" (without ever mentioning saliva as an example for such a carrier), he cannot give a hint to "essentially anhydrous compositions for oral administration without liquid" either.

Additionally, Ventouras does not teach that his compositions are like jam or jelly and that they can form a coherent, mouldable viscous mass, as the Office stated on page 10 of the Action. Ventouras actually teaches at column 4, lines 13-16, that his suspensions may be used to administer pharmaceutically active compounds like a jam or a jelly in a spoon. The compositions of Ventouras are, after wetting with water, dispersions or suspensions, but not a "coherent, mouldable, viscous particle paste" as asked for by instant claims 1 and 25. It is observed in this context that the "swellable pellets" Ventouras prepares in his example have an outer-most coating consisting of 37.5% parts by weight of ethylcellulose (used as 30% aqueous dispersion-Aquacoat ECD-30), of 25 parts by weight of talc and of 12.5 parts by weight of hydroxypropylmethylcellulose (Pharmacoat 603). The major components ethylcellulose and talc are not rapidly swellable in contact with water. This outermost coating is consistent with Ventouras' requirement that the pellets be dispersible and do not stick together, but is in contradiction to feature c) of his claim 1. It is in the applicant's view not certain how the skilled person reading Ventouras would resolve this contradiction.

Applicant respectfully submits that claim 23 is believed to be highly inventive over the cited art, in view of the amendments to independent claim 1. There is not a single disclosure in the cited documents that a composition according to claim 1, which is now asked to be "essentially anhydrous", could be administered to the mouth "without liquid and without chewing" (claim 1). Therefore the skilled person could not take from the cited prior ~~art any hint to provide a medicinal product pack containing an essentially anhydrous~~ composition according to claim 1 with instructions that this composition be taken by direct administration to the mouth without liquid and without chewing, as asked by claim 23. The presently claimed invention allows the administration of active compounds starting from an

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anhydrous composition, without the need of extra clean water which may be difficult to provide in some geographic areas, by forming a sticky paste through the action of the saliva formed by the salivation enhancer present in the outer coating (typically 0.2-4.0 ml saliva, depending on the amount of administered composition). It is observed that the saliva only causes the outermost border of the viscous particle paste to become slippery, so that the paste does not adhere to the oral mucosa or the teeth, but leaves the hydratable polymer in the interior of the particle paste sticky enough to cause the particles to form a coherent particle paste which can be swallowed as a whole without coarse feeling in the throat.

Where the prior art fails to suggest a result-effective variable, the claimed invention cannot be obvious. See *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977), where Antonie claimed an apparatus for treating waste water. The apparatus included a tank having continuously rotating semi-immersed contactors (discs). Antonie discovered that the ratio of tank volume to contactor area of 0.12 gals/sq. ft. maximized the treatment capacity of the equipment. The Patent Office cited a single reference disclosing the same basic structure, but lacking any disclosure of a tank volume to contactor ratio of 0.12. Indeed, the reference did not suggest any reason to calculate the tank volume to contactor area ratio, much less to select a specific magnitude. The Patent Office still considered an apparatus having the claimed ratio an obvious modification of the prior art apparatus. In the Patent Office's view, optimizing efficiency by varying parameter magnitude represented a mere matter of mechanical experimentation. In reviewing the Board's decision, the CCPA stated that an evaluation of the obviousness of the invention as a whole requires looking "not only to the subject matter which is literally recited in the claim in question (the ratio value) but also to those properties of the subject matter which are inherent in the subject matter and are disclosed in the specification. Similarly, Applicant have recited a specific function for the salivating agent under specified conditions. There is no recognition of the result effective variable in any of the cited references. Accordingly, the present claims should not be rejected.

Furthermore, in evaluating the invention as a whole, the Office must consider the functional language in the claim. See, e.g., *In re Caldwell*, 319 F.2d 254, 138 USPQ 243 (CCPA 1963), where Caldwell appealed the claims directed to methods of stimulating growth of ruminants, poultry, and swine using effective amounts of aspirin in feed rations. The cited art taught administering aspirin to children and rats, without any suggestion of stimulating

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growth. The Office rejected the claims as obvious over a reference that did not satisfy the claimed functional language. The CCPA reversed, stating that the real novelty is as defined in all of the appealed claims -- stimulating the growth of ruminants, poultry, or swine by feeding them aspirin for that purpose. The prior art did not suggest such a method. Patentability resided in the unobvious use of aspirin for growth promotion. Similarly, the Office should consider the functional limitations of the claimed invention; and if it did so, it would come to conclusion that the claimed invention is indeed non-obvious.

Additionally, under *KSR Intern'l Co. v. Teleflex Inc.*, Case No. 04-1350, 550 U.S. ____ (2007), the presently claimed invention should be patentable over the cited references because the improvement in storage stability is a not a predictable use of prior art elements according to their established functions. The presently claimed invention is not an example of using prior techniques in the same way. Further, to reject the present claims, the Office cannot make some conclusory statements (see page 14 of the slip opinion *KSR*); instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Even if the person of ordinary skill in the art is a person of ordinary creativity, there is no way he or she can think about administering without water when the prior art is totally silent about this concept. There is no common sense solution here since the problem of administering without water was not even recognized by the art.

In *United States v. Adams*, 383 U.S. 39 (1966), discussed in the *KSR* opinion, the patent was directed to a wet battery that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The U.S. Supreme Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. The U.S. Supreme Court rejected the Government (losing party)'s argument that Adam's battery was obvious. The U.S. Supreme Court considered the fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams' design was not obvious to those skilled in the art. Similarly, here the claimed invention provides more than a predictable yield, i.e., the claimed invention forms a mouldable viscous particle paste when placed in the mouth, which was totally unpredictable at the time of the invention.

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In view of the foregoing, Applicant respectfully submits that the presently claimed invention of claim 1 and dependent claims 3, 6-9, 16-17, 21, and 23 are non-obvious and patentable over Ventouras and Schultz.

2. Claims 1-4, 6-12, 14-20, and 22-23 stand rejected under 35 USC 103(a), as allegedly unpatentable over Ibsen (USP 5,288,500). As Applicant has amended claim 1, the obviousness rejection is no longer applicable. The presently claimed invention is non-obvious.

Amended claim 1 requires an "amount which is effective, upon said oral administration of the composition, in promoting a flow of saliva which is sufficient to form said coherent, mouldable, viscous particle paste within less than 20 seconds". Ibsen on the other hand uses a weak acid, such as citric or tartaric acid, to regulate the pH of the medium for pH-sensitive viscosity-increasing agents (= pH sensitive gelling agents). Ibsen does not use these acids to control the viscosity, as was held by the Office. Since Ibsen indicates generally "hydrophilic polymers" as the gelling or swelling agents (column 5, lines 9-19; see also column 9, lines 11-23 for further such polymers) said pH-sensitive gelling agents must be polymeric. They thus contain a large number of pH-active groups per polymer molecule, which in turn necessitates a large molar excess of pH-regulating weak acid to shift the pH to a range where the gelling agent has the desired viscosity. Consequently, the amount of tartaric or citric acids effective to shift the pH of the medium to a useful range would be appreciably higher than their amount "which is effective, upon said oral administration of the composition, in promoting a flow of saliva which is sufficient to form said coherent, mouldable, viscous particle paste within less than 20 seconds".

The passage in Ibsen where tartaric and citric acids are disclosed as pH regulating agents is on column 9, line 65 to column 10, line 12. In this passage Ibsen states that it is important to prevent the formation of a "highly viscous medium throughout the aqueous carrier". Ibsen seeks, in contrast to instant claim 1, to prevent the formation of a coherent particle paste; which is in line with his general teaching that the viscosity should only be increased in the immediate vicinity of the particles (abstract, column 4, lines 2-8).

Furthermore in the same passage it is disclosed that in this embodiment the viscosity-

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increasing substance is in the aqueous carrier, not in the coating layer. In contrast thereto, instant claim 1 asks that the hydratable polymer be present in the outermost coating layer. In citing this passage of Ibsen, the Office has disregarded important differences to claim 1. Further, the Office should recognize that Ibsen teaches away from the presently claimed invention by teaching that formation of a coherent particle paste should be prevented. When the prior art teaches away from certain combination of known elements, discovery of a successful means of combining them is more likely to be nonobvious. *KSR* at page 12, citing *United States v. Adams*.

In addition, a person of ordinary skill in the art does not receive any hint from Ibsen to optimize the amount required to obtain a sufficient saliva flow when the cited reference teaches compositions only for dispersion in water prior to administration.

In view of all of the foregoing, the obviousness rejection over Ibsen should be withdrawn.

3. Claims 5 and 13 stand rejected under 35 USC 103(a), as allegedly unpatentable over Ibsen in view of Kobayashi (US 5,476,668). Applicant respectfully disagrees. Kobayashi does not provide either a hint to the features of claim 1 which are not obvious from Ibsen, in particular to the amount of salivation-promoting agent which is effective to obtain a sufficient flow of saliva. Accordingly, the rejection should be withdrawn.

4. Claims 1-4, 6-12, 14-19, and 22 are rejected under the doctrine of obviousness-type double patenting rejection as allegedly unpatentable over USP 6,709,678 (Gruber). Applicant encloses herewith a Terminal Disclaimer as an administrative convenience to remove the rejection. The filing of a Terminal Disclaimer is not to be construed as acquiescence that the claimed invention is in fact obvious as the Office has claimed. *Quad Environmental Tech. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). Accordingly, the double patenting rejection should be removed. New claim 25 also should not be rejected on this basis.

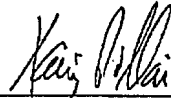
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Conclusion

Applicant respectfully submits that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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